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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,422	10/07/2005	Vinod Chintamani Malshe	044-P001	6676

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EXAMINER	
HELM, CARALYNNE E	
ART UNIT	PAPER NUMBER
1615	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,422	MALSHE ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☒ Claim(s) *5-18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/16/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification (Title)

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The term "novel" used in the title does not confer any additional description to the invention. According to MPEP 606,"The title should be brief but technically accurate and descriptive and should contain fewer than 500 characters. Inasmuch as the words 'new,' 'improved,' 'improvement of,' and 'improvement in' are not considered as part of the title of an invention, these words should not be included at the beginning of the title of the invention and will be deleted when the Office enters the title into the Office's computer records, and when any patent issues."

Claim Objections

Claims 5-18 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can only depend from multiple other claims in the alternative. In addition a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 5-18 have not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the

invention. The phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation "aliphatic polyesters derived from fatty diacids and fatty diols both with even number of carbon atoms", and the claim also recites "particularly polyethylene sebaccate" which is the narrower statement of the limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Shalaby et al. (U.S. Patent No. 4,186,189 – see 892).

Shalaby et al. teach a pharmaceutical composition with one or more drugs and the absorbable (biodegradable), aliphatic polyester, poly(alkylene oxalate) (see claim 1; instant claim 1). Instant claim 1 recites a product-by-process in that the claimed polymer is derived from diacids and diols. According to MPEP 2113 " '[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.' *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)." The alkylene chain in Shalaby et al. is taught to be C_{16} while the "diacid-derived" component is from the two carbon oxalic acid, thereby meeting the limitations of the claimed product (see claim 1). Further, Shalaby et al. teach that the drug polymer ratio is from 1:99 to 99:1 (see claim 1; instant claim 4). In addition, the drug is taught to be an endocrine agent (hormone) (see claim 4; instant claim 3). Therefore, claims 1 and 3-4 are unpatentable over Shalaby et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquires of Graham v. John Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shalaby et al.

Shalaby et al. teach a pharmaceutical composition with an aliphatic, degradable polyester and drug where the polymer is derived from fatty diacids and diols with even numbers of carbons (see ***Claim Rejections - 35 USC § 102*** for 1 and 3-4 claims above). Shalaby et al. also teach a variety of drugs suitable for incorporation in their invention. These drugs include

anti-hypertensive agents (cardiovascular agents), analgesics, steroids, chemotherapeutic agents (anti-cancer agents), heparin (anti-coagulant), anti-inflammatory agents, agents affecting the central nervous system (epilepsy remedies and muscle relaxants), trypsin (fibrinolytics), agents affecting metabolic diseases (hyperlipidemic remedies) (see column 3 lines 14-45; instant claim 3). Shalaby et al. also teach that their exemplified list of drugs is not limiting and that other drugs could be used in the pharmaceutical composition (see column 3 lines 46-47). Since biodegradable polymers are well known in the art for their use in drug delivery, the incorporation of other known drugs, not specifically disclosed by Shalaby et al., for their known purpose would also have been obvious to one of ordinary skill in the art at the time of the invention. Therefore claims 1 and 3 are obvious over Shalaby et al.

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Penhasi (U.S. PGPub No. 2003/0208259) in view of Farachi et al (U.S. Patent No. 6,562,939) and Zhu et al. (Chinese Chemical Letters 2001 12(7):589-592).

Penhasi teaches a stent with a polymer and drug (see paragraph 22-24; instant claim 1). Specifically Penhasi teaches the drug being incorporated in a polymer matrix where, polyethylene sebacate is taught as one of the preferred polymers (paragraph 35 line 33-34; instant claims 1 and 2). Farachi et al. teach that the polyalkylene sebacates of their invention are particularly good for their mechanical strength, desirable molecular weights, and degradability (see column 2 lines 41-47 and 63-65; instant claim 2). Farachi et al. also exemplify polyethylene sebacate as a particular polyalkylene sebacate (see column 4 lines 57-59; instant claim 2). Neither Farachi et al. nor Penhasi teach particular molecular weights of the aliphatic polyesters of their inventions. Zhu et al. teach that aliphatic polyesters are preferred among biodegradable polymers due to their better biodegradability properties and that this property

depends upon their molecular weight (see paragraph 1 lines 5-8; instant claim 2). In addition, Zhu et al. also teach molecular weights that range from approximately 800 to approximately 20400 for degradable aliphatic polyesters (see tables 1 and 2). Thus in view of teachings of Zhu et al. and Farachi et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a polyethylene sebacate with a molecular weight between 800 and 20400 along with a drug in the invention of Penhasi. Further, since the molecular weight of polyesters is known to effect its degradation the routine optimization of this parameter would have been well within the purview of one of ordinary skill in the art at the time of invention as well. Therefore claims 1-2 are obvious over Penhasi in view of Farachi and Zhu et al.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Michael P Woodward/
Supervisory Patent Examiner, Art Unit 1615